Application Cover Page

Name of Clinical Laboratory *(Legal name as it will appear on the contract)*

Business Address *(Street address, P.O. Box, City, State, Zip Code)*

Mailing Address *(Street address, P.O. Box, City, State, Zip Code)*

Person authorized to act as the contact for this clinical laboratory in matters regarding this application:

Printed Name *(First, Last)*:	Title:
Telephone number: ( )	Fax number: ( )

Person authorized to bind this clinical laboratory as the sole proprietor, partner, corporate officer, or government official in matters regarding this application or the resulting contract:

Printed Name *(First, Last)*:	Title:
Telephone number: ( )	Fax number: ( )

Signature of Authorized Representative (sign in blue ink)	Date:

Laboratory Director

Printed Name *(First, Last)*:	Title:

Signature of laboratory director as identified on CLIA certificate (sign in blue ink)	Date:

Person who completed the Application

Printed Name *(First, Last)*:	Title:

Telephone number: ( )	Date:

Signature of Author (sign in blue ink)

Required Attachment / Certification Checklist

Application format and content.		**Confirmed by DHS**
☐ Yes ☐ No	The clinical laboratory complied with the Application format requirements and submitted one original Application, five (5) copies, two (2) redacted copies and one (1) copy of the original on one (1) CD-ROM. My Application is assembled in the following order: 1) 1-CD-ROM 2) 1-Original copy 3) 2-Redacted copies 4) 5-Copies of the original	☐ Yes ☐ No
☐ Yes ☐ No	Application Cover Page (Attachment 1)	☐ Yes ☐ No
☐ Yes ☐ No	Table of Contents	☐ Yes ☐ No
☐ Yes ☐ No	Fiscal and Management Anti-Fraud Activities Section	☐ Yes ☐ No
☐ Yes ☐ No	Clinical Laboratory Compliance Program	☐ Yes ☐ No
☐ Yes ☐ No	Project Personnel Section	☐ Yes ☐ No
☐ Yes ☐ No	Facilities, Resources and Equipment Section	☐ Yes ☐ No
☐ Yes ☐ No	Accessibility Section	☐ Yes ☐ No
☐ Yes ☐ No	Forms Section	☐ Yes ☐ No

Form section with the following attachments / forms:		**Confirmed by DHS**
☐ Yes ☐ No	Attachment 2, Required Attachment /Certification Checklist	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 3, Required Forms and Licenses	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 4, Certification of Qualifications	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 5, Justification Sheet (If applicable)	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 6, Applicant Information Sheet	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 6a; Proof of Liability Insurance	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 6b; Proof of Professional Liability Insurance	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 6c; Proof of Worker's Compensation Insurance	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 9, Conflict of Interest Compliance Certificate	☐ Yes ☐ No
☐ Yes ☐ No	Attachment 10, Owner(s)/Laboratory Director(s) Agreement of Terms & Conditions	☐ Yes ☐ No

Name of Clinical Laboratory:	
Printed Name/Title of the person authorized to bind this clinical laboratory as the sole proprietor, partner, corporate officer, or government official:	
Signature (sign in <u>blue</u> ink)	Date:
Printed Name of laboratory director as identified on the CLIA certificate:	
Signature (sign in <u>blue</u> ink)	Date:

REQUIRED FORMS AND LICENSES

Qualification Requirements. I certify that the clinical laboratory submitted the following items: (If No, please explain on Attachment 5.)		**Confirmed by DHS**
☐ Yes ☐ No	**1.** A copy of the most recent CLIA Laboratory Personnel Report – Form HCFA 209 (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**2.** A copy of the most recent State of California Laboratory Personnel Report – form LAB 116A (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**3.** The name, business address and telephone number of the person(s) or entity responsible for billing during the calendar year of 2003, and provide copies of contractual agreements, if any. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**4.** The name, business address and telephone number of the person(s) or entity responsible for obtaining new clients for the clinical laboratory and provide copies of contractual agreements, if any. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**5.** A list of all licensed practitioners who perform the professional component of clinical laboratory tests or examinations for the clinical laboratory separately identifying those licensed practitioners who independently bill for the professional component of clinical laboratory tests or examinations utilizing the CLIA certificate of the Applicant. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**6.** A copy of the business name, address and CLIA number of any other clinical laboratory where the Contractor's laboratory director also serves as a laboratory director. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**7.** A copy of the laboratory director's current medical license or license as a bioanalyst or director pursuant to Division 2, Chapter 3, Business and Professions Code. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**8.** A copy of the contractual agreement between the clinical laboratory and laboratory director or specific explanation if no agreement exists. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**9.** A copy of the local business license. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**10.** A copy of the California Clinical Laboratory License. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**11.** A copy of the lease agreement for the clinical laboratory's business address. If there is no agreement, submit the name, address and telephone number of the property owner. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**12.** A copy of the HIV testing authorization from the State of California, if HIV tests are performed. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**13.** A summary sheet of the proficiency test percent score results for all regulated analytes for the calendar years 2002 and 2003. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**14.** A listing of ten current third party payors as defined in the Glossary of Terms (See Appendix 1) and a documentation to verify proof of payment. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No

☐ Yes ☐ No	**15.** A listing of any clinical laboratories the Applicant used as a reference clinical laboratory during calendar year 2003. For each reference clinical laboratory, include the full name as shown on the CLIA certificate, the business address and telephone number of the clinical laboratory, CLIA certificate number. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**16.** A copy of the document(s) to support ownership and maintenance of each item of clinical laboratory equipment. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**17.** A description of how accessible the clinical laboratory services are to Beneficiaries. (Accessibility Section)	☐ Yes ☐ No

Name of Clinical Laboratory:	
Printed Name/Title of the person authorized to bind this clinical laboratory as the sole proprietor, partner, corporate officer, or government official:	
Signature (sign in <u>blue</u> ink)	Date:
Printed Name of laboratory director as identified on the CLIA certificate:	
Signature (**sign in <u>blue</u> ink**)	Date:

CERTIFICATION OF QUALIFICATIONS

Please answer the following questions: (Provide explanations to any "No" answers on Attachment 5.)	
1. Does the clinical laboratory operate in conformity with Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code and the regulations adopted thereunder, and Section 263a of Title 42 of the United States Code and the regulations adopted thereunder?	☐ Yes ☐ No
2. Does the clinical laboratory have a current and active Medi-Cal provider number as issued by the Medi-Cal Provider Enrollment Branch of the California Department of Health Services and meets the Medi-Cal Standards for Participation as described in Title 22, California Code of Regulations, commencing with Section 51200 and meet the enrollment requirements as set forth in the Welfare and Institutions Code, commencing with Section 14043, and the regulations adopted thereunder, including the new Section 51200.01, Established Place of Business?	☐ Yes ☐ No
3. Is the clinical laboratory in compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 regarding security and privacy of protected health information and the use of industry-wide standards for health care information?	☐ Yes ☐ No
4. The clinical laboratory is willing to comply with the terms, conditions and contract exhibits addressed in the RFA Section "N" entitled, "Contract Terms and Conditions".	☐ Yes ☐ No
5. (Corporations) The clinical laboratory is in good standing and qualified to conduct business in California.	☐ Yes ☐ No

Has the clinical laboratory or any of its owners as defined in Appendix 8, or laboratory director been convicted of the following conduct, been found liable in any civil proceeding or entered into a settlement in lieu of a conviction within the last ten years from the date this certification is signed? (Provide explanations to any "Yes" answers on Attachment 5)	
6. A criminal offense related to the delivery of an item or services under Medicare or Medicaid in any state?	☐ Yes ☐ No
7. A conviction of any felony, or any misdemeanor involving fraud, abuse of the Medi-Cal program or neglect or abuse of any patient or beneficiary, or otherwise substantially related to the qualifications, functions, or duties of a provider of service?	☐ Yes ☐ No
8. A conviction under federal or state law of a felony or misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct against a health care program financed by any federal, state, or local government agency?	☐ Yes ☐ No
9. A conviction under federal or state law of a felony or misdemeanor relating to unlawful manufacturing, distributing, prescribing, or dispensing of a controlled substance?	☐ Yes ☐ No
10.A conviction of any felony or misdemeanor involving fraud or abuse in any government program?	☐ Yes ☐ No
11.A conviction of a criminal offense in connection with the interference with or obstruction of any investigation into health care related fraud or abuse?	☐ Yes ☐ No
12. Been found liable for fraud or abuse in any civil proceeding, or entered into a settlement in lieu of conviction for fraud or abuse in any government program?	☐ Yes ☐ No

Has the clinical laboratory: (Provide explanations to any "Yes" answers on Attachment 5)	
13. Been excluded, suspended, terminated or involuntarily withdrawn from a federal or state health care program?	☐ Yes ☐ No
14. Had a license, certificate or other approval to provide health care revoked, suspended, or excluded by a federal, California or other state's licensing, certification, or approval authority or has otherwise lost that license, certificate, or approval, or surrendered that license, certificate or approval while a disciplinary hearing on that license, certificate, or approval was pending?	☐ Yes ☐ No
15. Been found by any licensing, certifying, or professional standards board or agency to have violated the standards or conditions related to license, certification, or quality of care?	☐ Yes ☐ No
16. Failed to pay fines or overpayments assessed by the Medicare or Medicaid program?	☐ Yes ☐ No
17. Has debt owing DHS and is making regular payments to reduce the debt?	☐ Yes ☐ No

Please answer the following questions: (Provide explanations to any "Yes" answers on Attachment 5)	
18. Has the clinical laboratory violated the Civil Monetary Penalties Law (42 U. S. C. 1320a-7a) or the statute entitled "Criminal Penalties for Acts Involving Federal Health Care Programs" (42 U.S.C. 1320a-7b)?	☐ Yes ☐ No
19. Has the director(s) or owner(s) owned or controlled an entity where a sanctioned individual or immediate family member (spouse, natural or adoptive parent, child, sibling stepparent, stepchild, stepbrother or stepsister, in-laws, grandparent and grandchild) has held an ownership or controlling interest? See **Appendix 8** for the definition of owner and laboratory director.	☐ Yes ☐ No
20. Is the clinical laboratory's license or Medi-Cal provider number currently suspended, revoked, or are Medi-Cal payments being withheld?	☐ Yes ☐ No

On behalf of the clinical laboratory named in this RFA and all of its owners and laboratory directors and co-directors I certify under the penalty of perjury that the above information is true and correct to the best of my knowledge.

Name of Clinical Laboratory:	
Printed Name/Title of the owner(s) or his or her delegated representative and the laboratory director authorized to bind the clinical laboratory:	
Signature (sign in <u>blue</u> ink)	Date:
Printed Name of laboratory director as identified on CLIA certificate:	
Signature (**sign in <u>blue</u> ink**)	Date:

Justification Sheet

Provide all responses to Attachment 3 and Attachment 4 in the space provided below. Include in each response the section name (i.e, Attachment 3 or Attachment 4) and the question number. Please make a copy of this page if additional space is required.

Applicant Information Sheet

A signature affixed hereon and dated certifies compliance with all RFA requirements. Our signature authorizes the State to verify the claims made on this certification.

Name of Clinical Laboratory	CA Corp. No. (If applicable)	Federal Tax ID No.

Social Security No. (If sole proprietor)	9-digit Medi-Cal Provider No.	Telephone No.	Fax No.

Business Address	City	State	Zip Code

Type of Business Organization / Ownership (Check all that apply)

Ownership
- ☐ Sole Proprietor
- ☐ Partnership
- ☐ Joint venture
- ☐ Association

Corporation
- ☐ Nonprofit
- ☐ For Profit
- ☐ Private
- ☐ Public

Governmental
- ☐ City/County, California State Agency, Federal Agency, State (other than California)
- ☐ Other: _____

Lab Type
- ☐ Solo Practitioner
- ☐ Non-Solo Practitioner

See Glossary for definitions

- ☐ Other: _____

Indicate applicable licenses and/or certifications possessed:

- ☐ CLIA Certificate
- ☐ California Clinical Laboratory License
- ☐ California Local Business License
- ☐ Accreditation

List name of Accrediting Organization

_____
_____
_____

- ☐ Other

_____
_____

Proof of Liability Insurance—Applicant must attach a copy of the certificate of insurance to this Attachment. Label as Attachment 6a

Name of Insurance Company	Insurance Policy No.	Date Policy Issued

Insurance Agent's Name	Telephone No.	Fax No.	Expiration Date of Policy:

Business Address	City	State	Zip Code

Proof of Professional Liability Insurance—Applicant must attach a copy of the certificate of insurance to this Attachment. Label as Attachment 6b

Name of Insurance Company	Insurance Policy No.	Date Policy Issued

Insurance Agent's Name:	Telephone No.	Fax No.	Expiration Date of Policy

Business Address	City	State	Zip Code

Proof of Workers Compensation Insurance—Applicant must attach a copy of the certificate of insurance to this Attachment. Label as Attachment 6c

Name of Insurance Company		Insurance Policy No.		Date Policy Issued
Insurance Agents Name:	Telephone No.	Fax No.		Expiration Date of Policy
Business Address	City		State	Zip Code

Signature of owner(s) or his or her delegated representative and the laboratory director authorized to bind the clinical laboratory. (Sign in blue ink)	**Date Signed**
Printed/Typed Name	**Title**
Signature of laboratory director as identified on CLIA certificate. (Sign in blue ink)	**Date Signed**
Printed/Typed Name	**Title**

This Attachment has been deleted from this RFA.

Mandatory Letter of Intent

Purpose	The purpose of this non-binding Mandatory Letter of Intent is to assist DHS in determining the staffing needs for the Application evaluation process and to improve future procurements.
Information requested	DHS is interested in knowing if the clinical laboratory intends to submit an Application or the reasons for not submitting an Application. Completion of this form is **mandatory**. **If this Mandatory Letter of Intent is not submitted, participation in the Medi-Cal program as a provider will be terminated and the provider number deactivated upon contract commencement.**
Action to take	Indicate the intention to submit an Application by checking item 1 or 2 below. Follow the instructions below the selection.

1. ☐ The clinical laboratory intends to submit an Application.

A. Check box number 1 if the above statement reflects the intention of the clinical laboratory.

B. Complete the bottom portion of this form and return it to DHS as instructed in the RFA Section F entitled, "Mandatory Letter of Intent".

C. Submit a copy of the current CLIA certificate for the clinical laboratory.

D. Submit a copy of the current specialty / subspecialty certificate(s) for the clinical laboratory.

2. ☐ The clinical laboratory does not intend to submit an Application for this project.

A. Check box number 2 if the statement in item 2 reflects the intention of the clinical laboratory.

B. Indicate the reason(s) for not submitting an Application by checking any of the following statements that may apply.

- ☐ The clinical laboratory does not have the appropriate CLIA.
- ☐ The clinical laboratory lacks sufficient staff expertise or personnel resources to meet the requirements.
- ☐ The clinical laboratory lacks sufficient experience (i.e., not enough or wrong type).
- ☐ The clinical laboratory believes the qualification requirements are too restrictive.
- ☐ Not enough time was allowed for Application preparation.
- ☐ Too much paperwork is required to prepare an Application response.
- ☐ Other commitments and projects have a greater priority.
- ☐ The clinical laboratory did not learn about the contract opportunity soon enough.
- ☐ The clinical laboratory does not provide the services that DHS is seeking.
- ☐ Other reason:

Complete the bottom portion of this form and return it to DHS as instructed in the RFA Section F entitled, "Mandatory Letter of Intent".

Person authorized to bind this clinical laboratory as the sole proprietor, partner, corporate officer, or government official in matters regarding this application or the resulting contract:

Name of Clinical Lab:	Medi-Cal Provider Number:
Printed Name *(First, Last)*:	Title:
Telephone number: ( )	Fax number: ( )
Signature of Authorized Representative (sign in blue ink)	Date:

Conflict of Interest Compliance Certificate

A. Contractor, subcontractors, or employees, officers and directors of the Contractor or subcontractors shall avoid conflicts of interests or the appearances of conflicts of interest involving the collection of specimens and personal information and/or the performance of clinical laboratory tests or examinations, including unwarranted disclosure of confidential information. Thus, DHS reserves the right to determine, at its sole discretion, whether any information received from any source indicates the existence of a conflict of interest.

B. The following instances that would be considered a "conflict of interest", include, but are not limited to:

1. An instance where the Applicant/Contractor or any of its subcontractors, or any employee, officer, or director of the Applicant/Contractor or any subcontractors or his or her immediate family offers, delivers or accepts any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise as compensation or inducement for referring patients, clients, or customers, in violation of Business and Professions Code section 650 et. seq.

2. An instance where the Applicant/Contractor or any of its subcontractors, or any employee, officer, or director of the Applicant/Contractor or any subcontractors or his or her immediate family holds a position of interest, financial or otherwise, which would allow use or disclosure of information obtained while performing services for private or personal benefit or for any purpose that is contrary to the goals and objectives of the contract.

3. An instance where the Applicant/Contractor or any of its subcontractors, or any employee, officer, or director of the Applicant/Contractor or any subcontractors or his or her immediate family provides, offers, or solicits any form of payment or gratuity for human blood or any other biological specimen provided for the purpose of clinical laboratory testing or examination or clinical laboratory practice, unless the person is serving as an agent of a clinical laboratory or another facility legally utilizing those specimens only for purposes of research or teaching or for quality assurance purposes, or is an entity licensed under Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code.

C. If DHS is aware of a known or suspected conflict of interest, the Applicant or Contractor will be given an opportunity to submit additional information or to resolve the conflict. An Applicant or Contractor with a suspected conflict of interest will have five (5) working days from the date of notification of the conflict by DHS to provide complete information regarding the suspected conflict. If a conflict of interest is determined to exist by DHS and cannot be resolved to the satisfaction of DHS, before or after the award of the contract, the conflict will be grounds for the Application to be deemed non-responsive and/or termination of the contract.

D. This Certificate shall bear the original signature of an official of the Applicant who is authorized to bind the Applicant.

E. This Certificate will be incorporated into the contract, if any, awarded from this RFA. It is understood that this requirement shall be in effect for the entire term of the contract. The Contractor shall obtain a completed Certificate from any proposed subcontractor and submit it to DHS prior to approval of the subcontractor by DHS.

F. The Contractor and each subcontractor shall notify DHS, Clinical Laboratory and Durable Medical Equipment Contracting Unit at P.O. Box 997413, 1501 Capitol Avenue, MS 4600 Sacramento, CA 95899-7413 within ten (10) working days of any change to the information provided on this Certificate.

G. If the Applicant has a suspected or potential conflict of interest, the Applicant shall attach to this form, a description of the relationship, a plan for ensuring that such a relationship will not adversely affect DHS, and procedures to guard against the existence of an actual conflict of interest.

The undersigned hereby affirms that: (check one)

☐ The statements above have been read and that no conflict of interest exists that would jeopardize the ability of the Applicant/Contractor to perform free from DHS influence.

☐ A suspected or potential conflict of interest does exist, and additional information (as described in C above) is attached along with a plan to address the possible conflict of interest.

Person authorized to bind this clinical laboratory as the sole proprietor, partner, corporate officer, or government official in matters regarding this application or the resulting contract:	
Name of Clinical Lab:	
Printed Name *(First, Last)*:	Title:
Telephone number: ( )	Fax number: ( )
Signature of Authorized Representative (sign in blue ink)	Date:

Owner(s) and Laboratory Director(s) Agreement of Terms & Conditions

Identify all laboratory directors, laboratory co-directors and owners (as defined in B&P Code Section 1211) of the clinical laboratory on the list below. Each identified laboratory director/owner must sign this **Attachment 10** and agree to all terms and conditions of said contract. Failure to identify all laboratory directors, co-directors and owners at the time this Application is submitted may deem the Application non-responsive. (If more space is required, copy this page for additional signatures).

Print Name | Title | Date

Signature (sign in blue ink)

Print Name | Title | Date

Signature (sign in blue ink)

Print Name | Title | Date

Signature (sign in blue ink)

Print Name | Title | Date

Signature (sign in blue ink)

Print Name | Title | Date

Signature (sign in blue ink)

Print Name | Title | Date

Signature (sign in blue ink)